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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/753,461	01/09/2004	Justin Goshgarian	PA1776 US (1737.2770000)	6424
28390 7590 09/29/2008 MEDTRONIC VASCULAR, INC. IP LEGAL DEPARTMENT 3576 UNOCAL PLACE SANTA ROSA, CA 95403				
EXAMINER SIMPSON, SARAH A				
ART UNIT		PAPER NUMBER		
3731				
NOTIFICATION DATE		DELIVERY MODE		
09/29/2008		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

rs.vasciplegal@medtronic.com

Office Action Summary

Application No.

10/753,461

Applicant(s)

GOSHGARIAN, JUSTIN

Examiner

SARAH A. SIMPSON

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4, 7-13, 15, 18-25, 27 and 29-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 7-13, 15, 18-25, 27 and 29-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This action is in response to the Applicant's amendment filed 3/20/2008. Accordingly, claims 3, 5, 6, 14, 16, 17, 26 and 28 are canceled and claims 1, 2, 4, 7-13, 15, 18-25, 27 and 29-34 are pending and present for examination.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 4, 7-13, 15, 18-25, 27, and 29-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cottone et al. (US 2004/0093058) in view of Ischinger (US 6,146,417).

Cottone discloses a stent with a tubular body, a flaring member, a short segment of the flaring member remaining parallel to a longitudinal axis of said tubular body in the expanded configuration, and a long segment being generally perpendicular to the body upon expansion (Figure 4B). Cottone also discloses a balloon catheter (530), a retaining structure (520), and is of module construction (Figure 4B). Cottone's flared portion is made of nitinol (paragraph 22). Cottone does not disclose the body being a cobalt-chrome alloy (specifically MP35N) and a weld used to join the flared portion and

the body portion. Cobalt-chrome alloys are well known in the art of making stents because they exhibit mechanical and chemical properties equivalent to platinum/tungsten alloys and titanium alloys (Lau et al. (US 5,873,906) column 13, lines 30-40). The use of a known material in a known manner to yield predictable results is considered obvious. Further, simple substitution of one known equivalent element for another to obtain predictable results would have been obvious to one of ordinary skill in the art at the time of the invention. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Cottone's body to include a cobalt-chrome alloy. Ischinger teaches welding as a means to connect to different materials into one stent (Column 2 Lines 21-37). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Cottone's stent to include Ischinger's welds. Such a modification allows for different materials to be connected giving stents a wider range of capabilities.

Cottone also does not explicitly disclose the lengths associated with the flaring member. However, the Examiner considers it to be within the purview of a person having ordinary skill in the art to adjust Cottone's flared portion to any desired length. Furthermore, Figure 4B shows the general relation between the short segment and the long segment of the flaring member. In this drawing, the relative lengths between the two segments are substantially equivalent to the claimed lengths. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Cottone's segments to the claim's lengths. Such a modification would provide desirable length characteristics for a variety of differently sized lumens.

Furthermore, there is a need for the long, perpendicular segments to be significantly longer than the short segments so that the device will be able to maintain its location. If the segments are too short, the segments will not maintain their proper expanded position, and the device will be susceptible to movement.

Claims 1, 2, 4, 7-13, 15, 18-25, 27, and 29-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vardi et al. (US 2002/0156516) in view of Cottone et al. (US 2004/0093058) and Ischinger (US 6,146,417).

Vardi discloses a tubular body having a longitudinal axis, a proximal end and a distal end; and at least one flaring member attached to the proximal end of the tubular body (fig. 6g), but fails to disclose the tubular body being constructed from cobalt-chrome alloy, the flaring member made of a nickel-titanium alloy and a weld connecting the members.

However, Cottone discloses a stent with a tubular body, a flaring member, a short segment of the flaring member remaining parallel to a longitudinal axis of said tubular body in the expanded configuration, and a long segment being generally perpendicular to the body upon expansion (Figure 4B). Cottone also discloses a balloon catheter (530), a retaining structure (520), and is of module construction (Figure 4B). Cottone's flared portion is made of nitinol (paragraph 22). Cottone does not disclose the body being a cobalt-chrome alloy (specifically MP35N) and a weld used to join the flared portion and the body portion. Cobalt-chrome alloys are well known in the art (Lau et al. (US 5,873,906) column 13, lines 30-40). The use of a known material in a

known manner to yield predictable results is considered obvious. Further, simple substitution of one known equivalent element for another to obtain predictable results would have been obvious to one of ordinary skill in the art at the time of the invention. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Cottone's body to include a cobalt-chrome alloy. Ischinger teaches welding as a means to connect to different materials into one stent (Column 2 Lines 21-37). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Vardi's stent with Cottone's structural elements to include Ischinger's welds. Such a modification allows for different materials to be connected giving stents a wider range of capabilities.

Cottone also does not explicitly disclose the lengths associated with the flaring member. However, the Examiner considers it to be within the purview of a person having ordinary skill in the art to adjust Cottone's flared portion to any desired length. Furthermore, Figure 4B shows the general relation between the short segment and the long segment of the flaring member. In this drawing, the relative lengths between the two segments are substantially equivalent to the claimed lengths. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Cottone's segments to the claim's lengths. Such a modification would provide desirable length characteristics for a variety of differently sized lumens. Furthermore, there is a need for the long, perpendicular segments to be significantly longer than the short segments so that the device will be able to maintain its location. If

the segments are too short, the segments will not maintain their proper expanded position, and the device will be susceptible to movement.

Vardi in view of Cottone and Ischinger disclose the invention substantially as claimed as stated above. However, because the Applicant has argued that Cottone's body and flared sections would not be connected with a weld, the Examiner is included Vardi as an example of well-known ostium stent. It would have been obvious to a person having ordinary skill in the art to modify Vardi's stent include Cottone's general shape and Ischinger's welds. Such a modification would allow for different materials to combine into one stent making the stent more adaptable to different situations. Also, the Examiner notes the use of a retaining structure to be taught by Cottone (Item 520), the claimed materials are considered well known, and the lengths of the flared portions are obvious. This rejection is specifically being made to show that flared portions are often attached directly to body portions. Cottone is not being used as the primary reference to avoid arguments that welds teach away from Cottone or would destroy Cottone. As stated above and below in the response to arguments, the Examiner does not consider welds to destroy the reference, but this rejection is an attempt to circumvent such reasoning.

Response to Arguments

Applicant's arguments filed 3/20/2008 have been fully considered but they are not persuasive.

The Applicant has argued that Ischinger does not disclose that different materials may be welded together, when in fact, Ischinger states, "...the loops are attached to each other by welding, soldering, gluing or similar technique. This leads to an advantage that different materials can be combined, in contrast to the prior art, where only one material is used" (column 2, lines 27-37). Therefore, Ischinger clearly teaches welding different materials together.

The Applicant has argued that Ischinger does not disclose welding a cobalt-chrome alloy and a nickel-titanium alloy but instead leaps to a third reference not relied upon in the rejection as discloses the materials used. The Examiner would like to note that the rejection to the materials being used in the stent was made by taking Official Notice and the additional reference, Lau et al., was not relied upon in the rejection, but only provided as directly corresponding evidence to support the prior common knowledge finding that cobalt-chrome alloys are well known in the art and it does not result in a new issue or constitute a new ground of rejection. Selecting known materials on the basis of suitability for the intended use is a matter of design choice and is within the general skill of a worker in the art and substitution of one known element for another to obtain predictable results is also old and well known in the art. Lau et al. was only additional evidence supporting this factor.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was

within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

The Applicant has argued that the Examiner has not provided a reason why one of ordinary skill in the art would have replaced the encapsulating membrane (300) of Cottone with a welded connection. Although Cottone discloses using a membrane that allows cellular in-growth, the reference does not preclude the use of welds in addition to the membrane. The body section and the flared section may still have a membrane while being connected by welds. The welds will increase the strength of the connection and still allow the membrane to encourage cell growth.

The Applicant has argued that Vardi et al. is used as a teaching reference and that the Examiner failed to provide a reason for modifying Vardi et al. to construct the flaring portion of a nickel-titanium alloy and the tubular portion of a cobalt-chrome alloy. On the contrary, Vardi et al. is used as the primary reference and the Examiner previously stated that "Cottone and Ischinger disclose the invention substantially as claimed as stated above" (page 4, lines 4-5) only to reduce the amount of repetitiveness in the Office Action. The rejection has been rewritten above to further clarify that selecting known materials on the basis of suitability for the intended use is a matter of design choice and it is within the general skill of a worker in the art to construct the flaring portion of Vardi et al. of a nickel-titanium alloy and the tubular portion of a cobalt-chrome alloy, as evidenced by Lau et al.

Although Vardi et al. does not disclose weld connecting the flaring member to the tubular member, Vardi et al. teach "any means of creating such a flared portion" can be used and Ischinger teaches it is advantageous to weld stents together in order to allow for different materials to be combined, as discussed above. Further, the rejection is only being made to show that flared portions of stents are often attached directly to body portions without the need of a membrane. All other rejections such as those dealing with segment sizes have previously been addressed above.

In general, the Examiner considers the claims to have three main elements. Firstly, nitinol and cobalt-chrome alloys are widely used in stent manufacturing, and it is known to make a multi-material stent. The use of known elements in a known manner to yield predictable results is considered obvious to a person having ordinary skill. As to the second contention, welds have been shown above and in the previously cited pertinent art to be well known. Again, welding two alloys together is not patentable over the prior art. The Applicant has clearly claimed "welds" to overcome any confusion as to whether the claims constituted product-by-process limitations, but these structural limitations are still considered obvious. A person having ordinary skill in the art would know to combine two different alloys via welding. Finally, stents with flared ends are known in the art to help keep the stent in place in a branch vessel. All of the claimed features are known. The combination of these features follows a logical progression because each individual feature offers at least some advantage, the combination of features does not involve novel enterprise, and the combination does not eliminate the

advantages of the individual features. For at least these reasons, the claimed invention does not overcome the prior art.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Lau et al. (US 5,873,906 discloses that cobalt chrome alloys are old and well known in the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SARAH A. SIMPSON whose telephone number is 571-270-3865. The examiner can normally be reached on Monday - Friday 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sarah A Simpson/
Examiner, Art Unit 3731

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731